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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,596	08/31/2001	Nobuko Yamamoto	35.C15718	7458

5514 7590 07/08/2004

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT PAPER NUMBER

1637

DATE MAILED: 07/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,596

Applicant(s)

YAMAMOTO ET AL.

Examiner

Jeffrey Fredman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Chee et al (Science (1996) 274:610-614)

Chee teaches a method for identifying an unknown base sequence present in a target single stranded nucleic acid (see abstract) comprising the steps:

(a) preparing a probe array in which single stranded nucleic acid probes are arranged as isolated spots on a substrate, the probes each having a base sequence complementary to one of plural base sequences expected to be the unknown base sequence (see page 610, column 2 to page 611, column 1),

(b) reacting a single stranded nucleic acid, which has a base sequence fully complementary to a base sequence of one of the single stranded nucleic acid probes and is fluorescence labeled with the probe array under conditions that single stranded nucleic acids complementary to each other form a double stranded nucleic acid (see figure 1, panel C, top array and page 613, note 12)

removing the unreacted labeled single stranded nucleic acid (see page 613, note 12 and note 13),

Art Unit: 1637

measuring fluorescence intensity of each spot of the probe array to obtain a first template pattern showing a relationship between location of the probes and fluorescence characteristics (see page 614, notes 15, 17 and 21)

(c) performing the same operation as the step (b) for each of the remaining single stranded nucleic acid probes and obtaining template patterns of each probe showing a relationship between location and fluorescent characteristics of the probes (see figure 1, panel C, top array, and pages 613 and 614),

(d) performing the same operation as step (b) using a sample containing the target single-stranded nucleic acid of unknown base sequence to obtain a sample pattern showing relationship between a position and fluorescent characteristic (see figure 1, panel C, bottom array and pages 613 and 614)

(e) comparing the sample pattern obtained in step (d) with n pieces of template patterns obtained in steps (b) and (c), to identify a template pattern showing substantially the same pattern as the sample pattern and identifying the base sequence of the single stranded nucleic acid used from the preparation of the identified template pattern as the unknown base sequence of the target single stranded nucleic acid (see page 611, figure 1 and column 1 and page 612, figure 2 and columns 1-3, where Chee expressly notes "The array was used to successfully detect three disease causing mutations in a mtDNA sample from a patient with Leber's hereditary optical neuropathy. In addition, we detected a total of seven errors and new polymorphisms from previously unsequenced regions (see page 612, column 3).")

(f) Chee further analyzed the probe arrays to calculate a mean value of fluorescent intensities (see page 614, note 18) and then a difference was calculated between the fluorescence intensity of a reference array without a mismatch and the mean value of fluorescent intensities of the double stranded nucleic acids having a one or greater base mismatch (see page 614, note 16 and page 611, column 3) and

(g) Chee expressly notes regarding comparison of one and two mismatches to a control that "The marked decrease in target hybridization intensity, over a span of 20 nucleotides, is shown for a single base polymorphism as position 16,223 (Fig. 2A). The footprint is enlarged when two polymorphisms occur in close proximity (within 20 nucleotides) (Fig. 2B).(see pge 611, column 2)". Chee analyzes each of the positions to show a relationship between location and the fluorescent characteristics of the probes (see page 614, note 16 and page 611, column 3 and figure 2).

(h) Chee compares the sample pattern obtained from the unknown with the known sample pattern to identify the base sequence (see page 612, column 3 and page 614, notes 16 and 18).

Chee determines a two valued pattern using two colors (see figure 2) and has a threshold intensity value (see page 614, note 18, where at least 50 counts above background is required).

Chee teaches probes in the range from 15 nucleotide oligomers (see page 610, column 3).

Chee teaches single base pair mismatch detection (see figure 1).

Response to Arguments

3. Applicant's arguments filed 2004 have been fully considered but they are not persuasive.

Applicant argues that the current method is distinguished from Chee because it uses as emphasized repeatedly by Applicant, "plural" template patterns. However, this argument is not persuasive for a variety of reasons.

The first and often central problem is that the claims include no requirement for "plural" template patterns. Claim 1 requires no more than two template patterns, a first pattern and a second pattern.

Second, even if the claims required the use of "plural" template patterns, it is indefinite what applicant means by this term. Applicant argues that the disclosure by Chee of four different probes is not a plural template pattern at page 8 of the response. But there is no element of the claims which distinguishes the multiple probes of Chee from the invention and Applicant does not specifically indicate, in a structural way, what constitutes the probes which from the "plural" template patterns. The claims are simply drawn to the use of probe arrays, with no specific requirement that the probes form a "reference dictionary". In any case, any probe set that permitted distinguishing one target sequence from another necessarily constitutes a type of a "reference dictionary" for the particular sequences of interest. So the probe set of Chee provides a "reference dictionary" for the probes used by Chee.

Applicant then argues that the a comparison of probe patterns only applies when there is a one to one relationship between the patterns and the template.

Art Unit: 1637

First, as noted above, the claims have no limitations regarding "plural" templates.

Second, when Applicant attempts to reconstruct Chee as Applicant views the reference to meet the invention, no specific requirement of the claim is identified which supports this analysis. The claim does not require four probes, or more than two probes, for each mutation. So this argument, with all due respect, does not represent a distinction of the claims whatsoever.

Chee remains anticipatory with regard to the claims.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

Art Unit: 1637

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jeffrey Fredman
Primary Examiner
Art Unit 1637
